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| 09/239,873      | 01/29/1999  | CINDIE M. LUHMAN     | LL11.12-0040        | 6642             |

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EXAMINER

LEVY, NEIL S

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1616     | 31           |

DATE MAILED: 09/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

69

Application No.

239873

Applicant(s)

Lyhman

Examiner

MC Guy

Group Art Unit

166

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**—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—****Period for Reply**

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A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

**Status** Responsive to communication(s) filed on 6/13/03 This action is **FINAL**. Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.**Disposition of Claims** Claim(s) 75-262 is/are pending in the application.

Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

 Claim(s) \_\_\_\_\_ is/are allowed. Claim(s) 75-262 is/are rejected. Claim(s) \_\_\_\_\_ is/are objected to. Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.**Application Papers** See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved. The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner. The specification is objected to by the Examiner. The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119 (a)-(d)** Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). All  Some\*  None of the CERTIFIED copies of the priority documents have been received. received in Application No. (Series Code/Serial Number) \_\_\_\_\_. received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

**Attachment(s)** Information Disclosure Statement(s), PTO-1449, Paper No(s). 28 Interview Summary, PTO-413 Notice of Reference(s) Cited, PTO-892 Notice of Informal Patent Application, PTO-152 Notice of Draftsperson's Patent Drawing Review, PTO-948 Other \_\_\_\_\_**Office Action Summary**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 75, 77, 79, 81, 83-248 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection of record is maintained as new claims are said to be reiterations of rejected claims. Claims still do not provide 50 grams/day, of which at least 50% passes to abomasums. Claims are to many alcohols, but only sorbitol is demonstrated, with sufficient support for xylitol, glycerol, but not the rest.

Claims 83, 84, 95, 96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what patentable weight to give to "significant" of 83, 84 versus "substantial" of 95, 96 in the context of the claim language.

Claims 75-262 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,440,447. Although the conflicting claims are not identical, they are not patentably distinct from each other because 6,440,447 now is the patent of 09/338,314, of which double patenting rejection was made-the rejection is maintained over the new claims consonant with the patent claims.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 75, 92-95, 104, 107, 109, 110, 113, 128, 129, 138-141, 153, 157, 161-163, are rejected under 35 U.S.C. 102(b) as being anticipated by Baalsrud et al 3959493.

Baalsrud provides fats and fatty acid protection of nutrients, ruminally protected, (col.6) with digestion in abomasums, (line 50-53) releasing glycerol (col.5) lines 43-50). Milk cows are addressed (col.7, bottom-top col.8), as best treated with stearic acid 100g. of fatty acid was fed as protected pellet component to ewes (about 10% of cow weight) thus equivalent to 1000g fed to a cow).

Enhanced milk production is shown to occur when the fat is used as ruminal protectant (col.5) lines 8-13).

Claims 75, 79 are rejected under 35 U.S.C. 102(b) as being anticipated by Merensalmi-4127676.

Although Merensalmi does not specify supplying to abomasums, or to protection, applicant's base claims' are seen as open to interpretation of supplying abomasums by simply letting the feed follow its Natural Course-from mouth to abomasums-since

Merensalmi did see the instant results, without knowing how or why, the method steps as claimed are still met.

Claims 75-77, 79-81, 83, 87-95, 99-114, 128, 129, 133-141, 145, 153, 157, 161-163, 167, 171, 175, 179, 183-185, 189, 193, 197, 201, 205-207, 219, 223, 227-229, 233, 237, 241, 245, 251-255, 258-262 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khalili et al 97 and Merensalmi, Makinen et al '82, and Remond, in view of Lister et al '84 and Cummings et al 5585134 or Baalsrud et al 39594937.

Cummings and Baalsrud (above) provide Rumen by pass means, for delivery of drugs and nutrients. The other references are directed at feeding small amounts of sugar alcohols to milking ruminants. Thus, all references would be known by one in the milking production arts.

Khalili, of record, fed glycerol and free fatty acids and showed increased fat, protein, lactose and milk production-glycerol and stearic, linoleic fatty acids were used, including stearic. However, Rumen by pass was not considered. Cummings prepared rumen by pass supplements, of fatty acids, including stearic, for example (col.3, lines 32-40) and glycerol (col.2, lines 52-60). Added bioactives include sugars (col. 4-2.), and sugar, sources-molasses.

Makinen show sugar alcohols, from molasses, including sorbitol, arabinitol, mannitol, xylitol, galactitol (p.1079) increased milk production components (p.1082).

Remond showed 50g/day sorbitol increased, but not statistically significantly, milk production (p.2, 3 translation).

Merensalmi showed molasses, as sugar alcohol source, and xylitol, arabitol, mannitol, when fed to cows increased milk production. Merensalmi attributes increases to passage through the rumen, stating xylitol is less degraded than sorbitol (col.3, top).

Lister further show (p.26, 27) penta sugars less degraded than xylitol, or sorbitol, but adaptation occurs, and often continued feeding degradation in the rumen is enhanced.

The cited references either use sugar alcohols at the instant low levels-50-100grams/day, or at up to 400g/day, and with added feed sources of alcohols, such as molasses, thus providing nutrient metabolic sources that would increase milk component production. Thus, it would have been obvious to one of ordinary skill in the art of feeding cows, to utilize glycerol, or sorbitol, or another sugar alcohol, xylitol, arabitol, mannitol, and other polyols, as from molasses, and shown effective when fed, by Merensalmi or Remond, in a rumen protected form, such as Cummings. Motivation to use Cummings is shown by Cummings as preventing degradation in the rumen of bioactives known effective utilized in the lower digestive tract. Merensalmi, Khalili, and remond show these bioactives include small amounts of the instant sugar alcohols with improvements in milk yield and/or milk component production resulting.

Applicant's arguments filed 7/13/03 have been fully considered but they are not persuasive. Applicant has, so far as examiner can determine from examination of the now rewritten as new 150 or so claims, combined those aspects of non rejected claims so as to presume allowability-however it's not clear that only those elements are now extant. A more telling problem is that suggested by the 2 newly supplied references,

sauer and Fisher-they both suggest that feeding various sugar alcohols at near the applicants levels-also shown, at these levels, by Remond-would provide increased milk fat, protein, lactose; thus, increased total solids; while objected to references; Merensalmi, Khalili showed increased milk yield. Applicant's support is seen as feeding a few of the sugar alcohols at lower levels than most, but not all, of the prior art references, and obtaining various milk component increases. Since, the prior art also does this, the only basis seen for separation is that of feeding the small amounts of specific alcohols-sorbitol-ruminally protected so that the majority of the ruminally protected alcohol enters the abomasum.

Examinant has been directed at fed animals, not application directly into the abomasums. As fed, prior art and instant claim language in essence is the same; for claim 75, 79, unprotected is anticipated. The declarations are not persuasive, as they are outside the claimed invention.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is 308-2412. The examiner can normally be reached on Tuesday- Friday 7:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.

Levy/tgd  
September 22, 2003



NEIL S. LEVY  
PRIMARY EXAMINER